UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	Civil Action No.
STERIS CORPORATION, a corporation;	)	
and WALTER M. ROSEBROUGH,	)	
and PETER A. BURKE, individuals,	)	
	)	
Defendants.	)	

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 332(a), and the inherent authority of this Court, to permanently enjoin and restrain STERIS Corporation, a corporation, and Walter M. Rosebrough Jr., President and Chief Executive Officer ("CEO") of STERIS, and Peter A. Burke, Ph.D., Senior Vice President and Chief Technology Officer of STERIS, individuals (collectively, "Defendants") from violating :

A. 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of device, within the meaning of 21 U.S.C. § 321(h), that are: (1) adulterated within the meaning of the Act, 21 U.S.C. § 351(f)(1)(B), in that they do not have an approved application for premarket approval ("PMA") in effect pursuant to 21 U.S.C. § 360e(a), or an approved application for an investigational device ("IDE")

under 21 U.S.C. § 360j(g); or (2) misbranded within the meaning of the Act, 21 U.S.C. § 352(o), in that a notice or other information respecting significant changes made to the devices has not been provided to the United States Food and Drug Administration ("FDA") as required by 21 C.F.R. 807.81(a)(3)(i); and

B. 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(f)(1)(B) of articles of device after shipment of one or more of its components in interstate commerce.

JURISDICTION AND VENUE

2. The Court has jurisdiction over the subject matter and over all parties to this action pursuant to 28 U.S.C. §§ 1331 and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

THE DEFENDANTS

4. Defendant STERIS Corporation is incorporated under the laws of the State of Ohio and is doing business at 5960 and 6100 Heisley Road and 6515 Hopkins Road, Mentor, Ohio 44060, within the jurisdiction of this Court.

5. Defendant Steris manufactures and distributes liquid chemical sterilizing processing systems, articles of device (hereafter "LCS Devices"), within the meaning of 21 U.S.C. § 321(h), including the STERIS SYSTEM 1, and accessories and components thereto, including, but not limited to, the STERIS 20 sterilant concentrate and the STERIS SYSTEM 1 trays/Quick Connects (collectively, the “SS1").

6. Defendant Walter M. Rosebrough Jr., is the President and CEO of STERIS. He is the most responsible individual at the firm. He has overall responsibility for

STERIS, and he is ultimately responsible for the manufacturing and distribution of the SS1.

7. Defendant Peter A. Burke, Ph.D., is a Senior Vice President and Chief Technology Officer of STERIS. He reports directly to Walter Rosebrough and is responsible for the oversight of the firm's research and development activities, which includes design changes to the SS1.

8. Defendants have been, and are now, engaged in manufacturing, packing, holding, and distributing LCS Devices, as defined by 21 U.S.C. § 321(h). STERIS manufactures, packages, and distributes the SS1, which is a tabletop system using a paracetic acid solution to reprocess endoscopes, bronchoscopes, and other medical instruments between patient uses.

9. Defendants' LCS Devices are manufactured from components shipped in interstate commerce and are distributed and sold outside the State of Ohio.

FACTUAL BACKGROUND

10. The sponsor of a medical device can submit a "premarket notification" to FDA pursuant to 21 U.S.C. § 360(k), known as a 510(k) submission, and obtain a decision from FDA that the device is "substantially equivalent" to another device exempt from premarket approval (a "predicate device"), i.e., a device previously approved or cleared by FDA. 21 U.S.C. § 360c(f). A new device is substantially equivalent to a legally marketed "predicate" device if (1) the new device has the same intended use and the same technological characteristics as the predicate device, or (2) it has the same intended use and different technological characteristics, provided the information

submitted in the premarket notification demonstrates that the new device is as safe and effective as the predicate and does not raise questions regarding safety and effectiveness different from those raised by the predicate. 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.100(b)(2). A manufacturer must submit a 510(k) to FDA at least ninety days before the manufacturer intends to introduce the device into interstate commerce. 21 U.S.C. § 360(k). If FDA makes a finding of substantial equivalence, the device is "cleared" for marketing. 21 U.S.C. § 360c(f)(1).

11. In 1988, the SS1 was cleared for marketing under premarket notification (510(k)) submission number K875280.

12. A new premarket notification must be submitted to FDA for a change or modification to a device that could significantly affect the safety or effectiveness of the device. After obtaining marketing clearance in 1988, STERIS made significant changes or modifications to the design, components, method of manufacture, and intended use of the SS1, that required the submission of new premarket notifications to FDA for review and clearance of the SS1 in accordance with 21 C.F.R. § 807.81(a)(3).

13. STERIS failed to submit any such new premarket submissions for any of the changes to the SS1 device since 1988.

DEFENDANTS CONDUCT AND VIOLATIONS

14. The lack of premarket clearance for the significant changes made to the SS1 since 1988 causes the SS1 to be adulterated within the meaning of the Act, 21 U.S.C. § 351(f)(1)(B), in that the SS1 lacks a PMA in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved IDE under section 520(g) of the Act, 21 U.S.C.

§ 360j(g). The SS1 is also misbranded within the meaning of the Act, 21 U.S.C. § 352(o), in that a notice or other information respecting the significant changes made to the device were not provided to the FDA as required by 21 C.F.R. 807.81(a)(3)(i). Thus, there is no assurance that the device is safe and effective or otherwise in compliance with the Act.

15. Defendants have been and are now violating 21 U.S.C. 331(a) by introducing and delivering for introduction into interstate commerce articles of device that are adulterated and misbranded, within the meaning of 21 U.S.C. § 351(f)(1)(B) and 21 U.S.C. § 352(o), as set forth above.

16. Defendants have been and are violating 21 U.S.C. 331(k) by causing the adulteration, within the meaning of 21 U.S.C. § 351(f)(1)(B), of articles of device, as set forth above, while those articles are held for sale after shipment of one or more of their components in interstate commerce.

PRIOR NOTICE

17. Defendants are well aware that their continued distribution of the SS1 violates the Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct.

18. On May 15, 2008, FDA sent a Warning Letter to Defendants, stating that there have been "significant changes or modifications in design" to the SS1 that require submission of a new premarket notification. This letter further advised Defendants that their "[f]ailure to promptly correct these violations may result in regulatory action being

initiated by the FDA without further notice . . . . [such as] seizure, injunction, and/or civil money penalties."

19. On December 11, 2008, Defendants had a regulatory meeting with the former Director of FDA's Center for Devices and Radiological Health ("CDRH") and members of FDA's Cincinnati District Office, CDRH's Office of Compliance, and FDA's Office of the Chief Counsel, to further discuss the May 2008 Warning Letter.

20. FDA also sent letters to Defendants on December 8, 2009, December 3, 2009, and November 3, 2008, requesting corrective action for the adulterated and misbranded SS1 devices.

21. Despite these warnings by FDA, Defendants have failed to submit a premarket notification for the altered SS1 device and obtain a new marketing clearance from FDA.

22. The United States is informed and believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and (k), in the manner alleged herein.

WHEREFORE, Plaintiff prays:

I. That Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and every person in active concert or participation with any of them, be permanently restrained and enjoined pursuant to 21 U.S.C. 332(a) from directly or indirectly doing any act or failing to take any action that causes:

A. a violation of 21 U.S.C. 331(a), by introducing or causing to be introduced into interstate commerce, or delivering or causing to be delivered for introduction into interstate commerce, any article of device, within the meaning of 21 U.S.C. 321(h), that is adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), or misbranded within the meaning of 21 U.S.C. § 352(o), while such article is held for sale after shipment in interstate commerce; and

B. a violation of 21 U.S.C. 331(k), by causing any article of device to become adulterated while such article of device is held for sale after shipment of one or more of its components in interstate commerce within the meaning of 21 U.S.C. § 351(f)(1)(B).

II. That the Court order Defendants and each and all of their officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, to cease manufacturing, packing, and storing any article of device at or from the manufacturing and distribution facilities located at 5960 and 6100 Heisley Road and 6515 Hopkins Road, Mentor, Ohio, or at any new facility, unless and until Defendants' obtain premarket clearance for the SS1.

III. That the Court award Plaintiff costs and such other relief as the Court deems proper.

Dated this 19th day of April, 2010

Respectfully submitted,

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